

### **REMARKS**

The Office Action dated July 1, 2004 has been carefully reviewed, together with the references cited by the Examiner, and the claims of the captioned application. For the reasons set forth below, it is believed that the claims are allowable over the prior art of record, and the application is in condition for full allowance.

#### **Double Patenting Rejection**

Claims 1-16 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-23 of U.S. Pat. No. 6,726,531, by Harrel.

Submitted herewith is a terminal disclaimer to overcome the obviousness-type double patenting rejection. Reconsideration of the rejection of claims 1-16 is respectfully requested.

#### **Rejections Under 35 U.S.C. § 102(e)**

Claims 1, 2, 5, 7-9, 10-12, 14 and 16 are rejected as being anticipated by U.S. Pat. No. 5,797,744 by Rosenberg.

The Rosenberg reference discloses a prophylactic cup for use with an abrasive paste to remove deposits on teeth and otherwise polish the tooth surface. The prophylactic cup of the Rosenberg reference, like conventional prophylactic cups, is constructed of an elastomeric material so as to be pliable and conform to the contour of the tooth. See the paragraph bridging columns 1 and 2 of the Rosenberg reference; column 2, lines 44-52; column 3, lines 61-65 and column 4, lines 7-10.

Claim 1 has been amended to specify that the shank portion and the working portion of the tool are constructed of a rigid material. This patentably distinguishes the invention of claim 1 over the Rosenberg reference, as a prophy cup could not be made of a rigid material and yet conform to the contour of the tooth to polish the surface thereof. Filed herewith is a Declaration by the Applicant who is one skilled in the field of periodontics. According to paragraph 11 of the Declaration, a prophy cup made of a rigid material would not work for its intended purpose, as it could not conform to the contour of the tooth and polish the surface thereof. As such, claim 1 is not anticipated by the Rosenberg reference.

Claim 1 has also been amended to broaden the claim by removing the word "smooth" in connection with the working area. Claim 1 still specifies that the "surface area" is adapted for preventing abrasion.

Claims 2, 5 and 7 are patentable for the same reasons set forth above in connection with claim 1.

Claim 8 is patentable, as the Rosenberg reference does not disclose an elongate groove formed parallel to an axial axis of the prophy cup.

Claims 9 and 10 are patentable for the same reasons set forth above in connection with claim 1.

Claim 11 is not anticipated by the Rosenberg reference for the following reasons. Claim 11 specifies a smooth surface area adjacent one or more depressions, where the depressions have an abrading mechanism therein. Amended claim 11 also specifies the method step of "preventing abrading of the surface of the non-compliant workpiece once the rough areas have

been removed *by engagement* of the smooth surface areas of the tool with the surface of the non-compliant workpiece.”

The Examiner has indicated that the “smooth surface” of the Rosenberg prophyl cup is the outside bottom edge. When the Rosenberg prophyl cup is being prepared for use, an abrasive paste is placed in the cavity of the prophyl cup. The prophyl cup is pressed against the tooth to be cleaned, and then rotated. During use, the outside bottom edge of the prophyl cup has the abrasive paste on it, and thus also serves as an abrasive carrier to abrade the surface of the tooth. In preparing the prophyl cup for use, the technician placing the abrasive paste in the cavity may also place the abrasive on the outside bottom edge, as the abrasive paste is going to end up there during use anyway. If the technician does not want the prophyl cup to cause any further abrasion, the tool is lifted from the surface of the tooth so the abrasive-covered outside bottom edge is no longer in engagement with the tooth. As long as the technician holds the prophyl cup in engagement with the tooth, the tooth will be abraded. The operation of the Rosenberg prophyl cup is confirmed by the Declaration by the Applicant, and specifically paragraph 12 thereof.

Accordingly, the method of use of the Rosenberg prophyl cup does not satisfy the claim limitation where abrasion is prevented when the non-abrasive surface of the tool is engaged with the workpiece. From the foregoing, claim 11 is not anticipated by the Rosenberg reference.

Claims 12 and 14 are believed to be patentable for the same reasons set forth above in connection with claim 11.

Independent claim 16 has been amended to specify a rigid working portion. Claim 16 has also been amended to remove the word “smooth.” For the same reasons noted above in connection with claim 1, claim 16 is patentable over the prior art of record.

**Rejections Under 35 U.S.C. § 103**

Claims 3, 4, 6, 13 and 15 have been rejected as being obvious over the Rosenberg reference, in view of U.S. Pat. No. 4,283,175 by Nash. The Examiner is relying on the Nash reference for its teachings of the use of an ultrasonic device providing abrasion using a sharp edge.

Claims 3, 4, 6, 13 and 15 are not made obvious by the teachings of the Rosenberg and Nash references for the following reasons. As noted above, the Rosenberg prophyl cup is constructed with an elastomeric material so that it conforms to the contour of the tooth surface. The Examiner does not indicate in the Office Action how or where the sharp metallic edge of the Nash ultrasonic scaler could be incorporated into the Rosenberg elastomeric prophyl cup. Absent such a suggestion in the cited references, a prima facie case of obviousness has not been established. In paragraph 20 of the Declaration, the Applicant does not believe that the metallic sharp edge of the Nash scaler could be incorporated into an elastomeric prophyl cup to provide any meaningful or useful results.

The Examiner also combines the teachings of the Nash reference for ultrasonic devices, with the Rosenberg reference for its teachings of a prophyl cup. The operational movement of the prophyl cup is accomplished by rotating the cup up to 1,500 RPM (see column 1, lines 18-24). It is submitted that the prophyl cup would be rendered inoperative if vibrated with the ultrasonic device described in the Nash reference. The ultrasonic vibrations generated by the device would be wholly absorbed by the elastomeric material of the prophyl cup, and thus there would not be any relative movement between the abrasive-covered elastomeric material and the tooth surface. This conclusion is confirmed by the Applicant, as noted by paragraph 17 of the Declaration.

From the foregoing, claims 3, 4, 6, 13 and 15 are not made obvious by the teachings of the Rosenberg and Nash references.

### **New Claims**

New dependent claims 17-23 have been added to the application. These new claims are patentable for the same reasons noted herein in connection with claims 1 and 11.

### **Gordon PCT Published Patent Application**

Published PCT international patent application WO 98/38928 by Gordon et al., is hereby made of record by the Applicant in the above-captioned patent application. Enclosed is a Supplemental Information Disclosure Statement, PTO form SB/08A and a copy of the Gordon et al reference. Although the teachings of the Gordon et al. reference have not been applied to the claims by the Examiner, set forth below is an analysis of the reference in view of the claims. The claims have been amended to distinguish over the Gordon et al. reference.

The Gordon et al. reference discloses various embodiments of an atherectomy device that is intended to reduce damage to the blood vessels or in vivo stints. The device is structured to remove deposits (such as calcified material) or growths forming occlusions in a person's blood vessel and revascularize the occluded vessel so that the flow of blood is restored. The Gordon et al. device is structured to function inside a compliant, tubular-shaped blood vessel.

The various embodiments of the Gordon et al. device have non-abrasive surfaces that do not cause excessive wear on the tubular-shaped vessel walls (page 5, lines 11-15). The non-

abrasive areas are positioned to minimize engagement of the vessel walls with the abrasive-covered areas. The abrasive-covered areas are positioned on the device to engage the deposits and growths.

The Gordon et al. device is rotated in a blood vessel that is occluded with deposits, while at the same time being guided by a wire. As the device proceeds through the occluded vessel, the deposits and growths are generally removed while attempting not to excessively damage the walls of the blood vessel.

It can be seen from the various figures of the operation of the Gordon et al. device that the device cannot be structured to remove substantially all of the deposits without the real chance of also damaging the vessel wall. As noted above, at page 5, line 15 of the reference, the aim of the Gordon et al. device is "not cause excessive wear on the vessel walls." Because the Gordon et al. device functions with the soft and compliant tissue of a blood vessel, the tissue will not be a straight tubular shape as depicted in Fig. 2 or 3 of the reference. Rather, a typical blood vessel will have bumps, ridges and irregularities, all of which can become engaged in the abrasive-covered areas and become correspondingly damaged. Certainly, where the vessels branch off to other smaller vessels, the irregularities in the branched vessels can be abraded by the abrasive-covered areas of the Gordon et al. device. Indeed, any tissue of the vessel that comes in contact with the abrasive-covered area of the device will be abraded and damaged.

In addition, it is extremely difficult for the Gordon et al. device to remove all of the deposits down to the tissue wall and not damage the wall. To do so would require that the diameter of the abrasive-covered area of the device exactly match the diameter of the blood vessel. This is not possible, as the inside diameter of all blood vessels changes along the length of the vessel. Blood vessels become smaller in diameter for distances further away from the

heart. In Fig. 3 of the reference, if the largest diameter of the abrasive-covered area is smaller than the inside diameter of the vessel, then not all of the deposits are removed. If the diameter of the abrasive-covered area is larger than the inside diameter of the vessel, then the wall of the vessel will be damaged. Accordingly, if reasonable results are to be achieved, then a different size device would have to be used each time the inside diameter of the vessel changed. While it is realized that a blood vessel is compliant and flexible, if the device were to stretch the wall of the vessel, it is believed that there would still be a tendency of the vessel wall to become engaged in the abrasive-covered areas of the device.

The foregoing analysis also applies to the Fig. 4 embodiment of the Gordon et al. reference. This embodiment most resembles the figures of the captioned application. In the Gordon Fig. 4/5 embodiment, the fluted areas are covered with a diamond abrasive to abrade the deposits and growths attached to the wall of the vessel. So as not to cause excessive damage to the wall of the vessel, the smooth non-abrasive areas (between the fluted areas) are formed radially outwardly and form raised areas in the device to help separate the vessel wall from the abrasive-covered areas. The function of the raised areas 102 (Fig. 5) is believed to be for the purpose of attempting to maintain the inside wall of the vessel spaced above the abrasive-covered areas. While this may reduce abrasion of the inside wall of the vessel, it also prevents all of the deposits from being removed from the wall. Since there are no dimensions of the various structures disclosed in the reference, it is assumed the details of the Gordon et al. device are much like that shown in the figures.

It is noted that the device disclosed in the Gordon et al. reference is specifically adapted for use with the soft and compliant tissue of a blood vessel. There is no suggestion that such device could function with other materials that are non-compliant, especially metals and other hard tissues such as that forming a tooth.

The invention of applicant is different from that disclosed in the Gordon et al. reference. Applicant's invention is best employed with hard and non-compliant workpieces, including metal, synthetic materials and hard tissues such bone and teeth. The tool according to one embodiment of the present invention is structured to have shallow grooves (captioned application, page 6, lines 4 and 7) filled with an abrasive material. The abrasive-covered grooves are adapted for removing calculus and tartar deposits on tooth surfaces, until the deposits are gone, but any abrasion of the tooth itself is prevented (page 9, lines 4-6). As disclosed in connection with the preferred embodiment of the instant invention, the grooves are very shallow and narrow, thereby preventing the hard and non-compliant material of the workpiece from being abraded. According to an embodiment disclosed in the application at page 8, paragraph [0016], lines 10-12) the depth of each groove can be in the range of 0.06mm - 0.5mm, and the width of each groove can be in the range of about 0.33mm - 1.0mm. These are very small dimensions as compared to that seen from the drawings of the Gordon et al. reference. A depth of about 0.06mm is a little less than the approximate thickness of a sheet of 20 lb bond office paper. The thickness of 20 lb office bond paper is about .097mm. A groove depth of about 0.5mm would be about the equivalent of five sheets of such type of paper. Attached hereto is a paper from the Internet indicating the thickness of various types of paper (see page 2 of 8). It can be seen that the groove structure of one embodiment of the invention is very different from that shown in the Gordon et al. reference.

Also disclosed in the captioned application (paragraph 17, lines 1-7), the edge of each shallow depression or groove can be rounded, and the abrasive material does not coat the rounded corners. This feature facilitates the ability of the device to remove the rough surface areas, but not damage the underlying smooth surface of the hard tooth material. Various dependent claims added to the application relate to this feature of the invention.

Claim 1 has been amended to specify that the shank portion and the working portion of the tool are constructed of a rigid material. In addition, claim 1 has been amended to specify that the shank portion of the tool is adapted to be held in a non-flexible manner by the power-driven implement. This is in sharp contrast with the teachings of the Gordon et al. reference, where the device is connected to the power-driven implement by a flexible shaft. The flexible shaft is necessary in order to maneuver the device through the circuitous path in a vessel. From the foregoing, claim 1 is patentable over the teachings of the Gordon et al. reference.

Claim 11 has been amended to specify a method of removing rough areas of a non-compliant workpiece. This contrasts with the Gordon et al. teachings which disclose a device specifically adapted for use with soft and compliant tissue material. Applicant's method claim 11 specifies that the rough areas of the non-compliant workpiece are removed by the abrading mechanism, and the rough areas are continued to be abraded down to the surface of the non-compliant workpiece. Moreover, claim 11 specifies that the rough areas are removed without removing portions of the surface of the non-compliant workpiece. This leaves a clean, smooth and non-damaged surface of the workpiece. The result achieved by Applicant's device is vastly different from that of the Gordon et al. reference for the reasons described above.

Claim 16 has been amended to specify that each depression is formed with an opening having a size so that the surface of the workpiece can not enter therein and become abraded. This contrasts with the Gordon et al. reference where the tissue of the vessel wall can enter the flutes, except for the raised smooth areas between the flutes which try to keep the vessel wall from entering into the abrasive-covered areas. Stated another way, if it were not for the raised areas identified by numeral 120, the tissue of the vessel would otherwise be more likely to enter into the abrasive-covered flutes. The openings to the fluted areas are nevertheless large enough to allow the soft tissue of the vessels to be abraded on contact therewith. For these reasons,

Appl. No. 10/804,348  
Amdt. dated Oct. 1, 2004  
Reply to Office Action of July 1, 2004

claim 16 is patentably different from the teachings of the Gordon et al. reference.

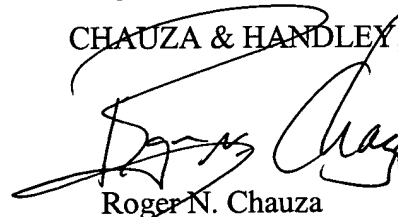
### **Claim Fee**

A check in the amount of \$ 82 is enclosed herewith to cover the cost of claims in excess of twenty, plus the fee for the terminal disclaimer. In the event that the check is missing or otherwise unavailable for payment of the required fees, authorization is given to deduct an amount sufficient to properly file this paper, from the deposit account of Chauza & Handley, LLP, 502112/HARR-24,972CO.

### **Conclusion**

From the foregoing comments and amendments, the claims of the application are believed to be allowable over the prior art of record. The Examiner is respectfully requested to reconsider the rejections and grant full allowance of the application.

Respectfully Submitted,  
CHAUZA & HANDLEY, LLP

A handwritten signature in black ink, appearing to read "Roger N. Chauza", is written over the printed name.

Roger N. Chauza

Reg. No. 29,753

Tel.: (972) 518-1414